

# Leukoreduction Experience in the American Red Cross



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# Failures of Leukoreduction in the American Red Cross

- What causes failures?
- Are they internal (never leave the blood center) or indicators of external failures?
- Do these failures beg for further action to protect the public?

# Methods of Producing Leukoreduced Units

- SD – Add a filter through sterile docking to a CPD red cell
- RC – Filter through an attached, in-line filter after the plasma and platelets are removed
- WB – Filter whole blood before components are made

# Categories and Numbers of Failures (from 3,619,169 LR RBCs)

1. Clots	13,003	
2. Cold Agglutinins	1,210	
3. Sickie pos	386	
4. User error	3,313	
5. RBC Recovery	15	*
6. WBC high	57	*
7. Unknown (failed)	11,173	
Total (not all shown)	30,457	

# Filter Failure Overall

- Of 3,619,169 red cells filtered, 30,457 failed
- Rate – 0.8%
- All failures listed here were not released
- 1% of leukoreduced red cells are required to be counted for WBC
- 57 failures of 3.6 million could indicate a 0.1% WBC failure rate
- FDA requires no more than a 5% failure rate

# Types of Filters and Failure Rate

Type of Filter	Failures	(%)	Total Filtered
Mgf 1 CPD	1,423	(1.1)	128,569
Mgf 2 CPD	34	(0.6)	5,732
Mgf 1 Ad -SD	9,934	(0.5)	1,880,290
Mgf 2 Ad -SD	1,424	(0.3)	460,947
Mgf 1 In-line	14,614	(2.3)	724,255
Mgf 1 In-line WB	1,599	(0.9)	174,007
Mgf 2 In-line WB	1,429	(0.6)	245,369

# Difference in Manufacturer Performance

- Manufacturer 1 had the highest failure rate and one category of filters was worse than the others
- The same filter Mfg accounted for 274/386 of the sickle trait failures
- Residual WBC failures were rare and evenly distributed among manufacturers



# Manufacturers

- Manufacturer 1, all filter types 2,733,114
  - failures - 27,722
  - rate - 1.0%
- Manufacturer 2, all filter types 712,048
  - failures - 2,887
  - rate - 0.4%



# Filter Failure - Investigation

Many potential causes

- All causes should be investigated
- One cause for all failures is not plausible
- Sickle trait testing alone does not solve leukoreduction failure problems in a constructive manner